

REMARKS

Claims 1, 2, 5-43, 51, 53-56 and 58 are pending following entry of the amendments presented hereinabove. Claims 1 and 51 have been amended, Claim 58 added, and Claims 3 and 4 canceled for the purposes of rewriting. Claims 44-50, 52 and 57 have been canceled without prejudice to the filing of a continuation application therefor. Cancellation of these claims in no way represents an acquiescence to the outstanding rejections; these claims have been cancelled merely to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000).

The specification has also been amended to correct a minor typographical error. The marked up version of the amendments to the specification and claims is attached hereto and is captioned "Version with Markings to Show Changes Made." The outstanding rejections will be addressed below in the order raised in the outstanding Office Action.

I. Section 112, first paragraph.

Claim 1-5, 8-15, 19-23, 26-35, 39-44, 47 and 51-56 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action states that the specification "while being enabling for the use of the alpha-galactosidase and its encoding nucleotide structure from *Thermotoga maritima*, does not reasonably provide enablement for the use of an alpha-galactosidase or its encoding nucleotide structure from either of *Thermotoga elfii* or *Thermotoga* sp. T2." (Office Action, page 2, second para.). Specifically, the Office action states that the claims are not enabled "with respect to the claims as they would be directed to the use of an alpha-galactosidase or its encoding nucleotide structure from either of *Thermotoga elfii* or *Thermotoga* sp. T2." (Office Action, page 2, third para.). This rejection is respectfully traversed below.

The "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (MPEP §2164.01, citing *In re Wands*, 858 F.2d 731, 737). With respect to the present application, the Examiner has acknowledged that the claims are enabled with respect to *T. maritima*, but has questioned enablement with respect to *T. elfii* and *T. sp. T2*. The Examiner has provided no objective evidence to doubt the veracity of Applicants' specification, or that the invention does not work as described. The Patent Office has the affirmative burden to set forth such evidence in order to establish even a *prima facie* case of non-enablement (MPEP § 2164.04; *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971)). This standard has not been satisfied in the present case. Thus, the rejection should be withdrawn.

As an initial point, the Applicants respectfully note that the independent claims do not require that the α -galactosidase enzyme be a recombinant enzyme produced using recombinant DNA technology. Instead, the enzyme may be isolated or purified from hyperthermophilic organisms, for example, as described by in the present application or by Duffaud et al., (1997) *Appl. Environmental Microbiol.* 63:169. According to the present specification, "the α -galactosidase may be natural, synthetic, semi-synthetic, or recombinant." (Specification, page 14, lines 19-21). Thus, enablement of the present claims does not depend on the availability of the sequences encoding the α -galactosidase enzymes from all of the recited species of *Thermotoga*.

Further, one skilled in the art would be able to isolate α -galactosidase or produce a recombinant enzyme from *T. elfii* and *T. sp. T2* without undue burden using no more than routine skill. The Examiner acknowledges that the *T. sp. T2* enzyme is known in the art (see, Koyama et al., (1990) *Applied and Environmental Microbiology* 56:2251) and that both the purified *T. maritima* enzyme and nucleic acid sequence are known. Yernool et al. discloses the *T. neapolitana* enzyme and

nucleic acid sequence, and the Duffaud et al. reference describes isolation of the native *T. neapolitana* enzyme. Thus, a number of isolated α -galactosidases and nucleic acid sequences encoding α -galactosidase enzymes from the genus *Thermotoga* are known in the art. One skilled in the art would be able to practice routine techniques of enzyme isolation (see, e.g., Duffaud et al., (1997) *Appl. Environmental Microbiol.* 63:169) or cloning in order to obtain the isolated α -galactosidase enzyme from *T. elfii* or the α -galactosidase coding sequences from *T. elfii* or *T. sp. T2*.

Finally, with respect to new Claim 58, Applicants note that this claim specifically recites *T. maritima*, and should therefore be free of the outstanding rejection.

In view of the foregoing arguments, it is submitted that the subject matter of the pending claims is enabled. Accordingly, it is respectfully requested that the outstanding rejection under § 112, first paragraph be withdrawn.

II. Section 112, second paragraph.

Claim 57 stands rejected on the basis of indefiniteness, the Office Action stating that the claim language "an edible soy protein isolate" is unclear. Claim 57 has been canceled, thereby obviating this amendment. Accordingly, it is requested that this rejection be withdrawn.

III. Objection to Claim 52.

Claim 52 stands objected to for being a substantial duplicate of Claim 44. Although Applicants respectfully disagree with this objection, it has been obviated as Claims 44 and 52 have been canceled.

IV. Johnson et al.

Claim 57 stands rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,936,069 by Johnson et al. As Claim 57 has been canceled, this rejection is moot. It is therefore respectfully requested that the outstanding anticipation rejection over Johnson et al. be withdrawn.

V. Liebl et al.

Claims 1-2, 7-8, 11-13, 15-18, 44-50 and 52 stand rejected under § 102(b) as anticipated by Liebl et al., (1998) *System. Appl. Microbiol.* **21**:1. The Office Action states that Liebl et al. describes a possible application of α -galactosidases in "the elimination of raffinose from sucrose syrups in sugar beet processing." (Office Action, at page 5, para. 5, quoting Liebl et al.). Claims 44-50 and 52 have been canceled. This rejection is addressed below with respect to pending Claims 1-2, 7-8, 11-13 and 15-18.

Independent Claim 1 has been amended to recite a method of hydrolyzing a galactose-containing oligosaccharide present in a "substrate intended for use as an animal feed or human food" by incorporating the recitations of dependent Claims 3 and 4. Claims 3 and 4 are free of the outstanding rejection; thus, Claim 1 as amended is also free of the present rejection over Liebl et al.

Accordingly, the Applicants submit that the subject matter of Claims 1-2, 7-8, 11-13, and 15-18 is novel and nonobvious over the cited Liebl et al. reference, and respectfully request that the outstanding anticipation rejection be withdrawn.

VI. Yernool et al.

Claims 1-56 stand rejected under 35 U.S.C. §103 (a) for obviousness over U.S. Patent No. 6,150,171 to Yernool et al. in view of Liebl et al. and PCT publication WO 98/24799 (Bylina et al.). This rejection is respectfully traversed below with respect to pending Claims 1, 2, 5-43, 51, 53-56 and 58.

The Patent Office has the initial burden under §103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicants respectfully note that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings in order to arrive at the claimed invention. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations (MPEP § 706.02(j)). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Federal Circuit has articulated the following legal test for obviousness: "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. . . . Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (emphasis added). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. *In re Geiger*, 2 USPQ2d 1276 (CAFC 1987). The mere fact that references can be combined does not render the combination obvious unless the prior art also suggests the desirability of the combination. *In re Fritch*, 23 USPQ 2d 1780 (CAFC 1992). The Court of Appeals for the Federal Circuit has addressed this issue and has stated that "[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Gordon*, 221 USPQ, 1125, 1127 (Fed. Cir. 1985) (emphasis added).

The Applicants respectfully contend that the Patent Office has failed to establish a *prima facie* case of obviousness in the present case as there is no motivation or suggestion to combine the cited references in the references themselves. Certainly, these references do not suggest the desirability of modifying the teachings of Yernool et al. by combination with Liebl et al. and/or Bylina et al.

With particular respect to new Claim 58, this claim is similar to Claim 1 except that it recites that the substrate is a "solid substrate intended for use as an animal feed." The recitation of "solid" is supported throughout the specification, including the working examples and the discussion of the terms "substrate", "animal feed", and the like, at pages 12-13 of the application.

In addition, Claim 58 recites that the method comprises a step of "steam heating the substrate." The inventors have discovered that the inventive enzyme compositions are active over a broad range of moisture conditions (see, e.g., Examples 4 and 5). The present application further states that "[p]referably the hyperthermophilic α -galactosidase is added prior to any steam treatment that the components of animal feed may undergo during processing." (Specification, page 29, lines 7-9). The inventors have discovered that the recited hyperthermophilic enzymes are advantageous for use in steam heating methods.

Finally, Claim 58 specifically recites that the hyperthermophilic α -galactosidase is from *T. maritima*.

In contrast, there is no disclosure in Yernool et al. of using a hyperthermophilic α -galactosidase from *T. maritima* to hydrolyze galactose-containing oligosaccharides in a solid substrate intended for animal feed in a method comprising steam heating. Further, there is no motivation for one of ordinary skill in the art to use a hyperthermophilic α -galactosidase in a method comprising a step of steam heating. Likewise, there is no such suggestion to be found in the secondary Liebl et al. or Bylina et al. references.

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Accordingly, in view of the foregoing, Applicants respectfully submit that the subject matter of the pending claims is non-obvious over Yernool et al. in any combination with Liebl et al. and Bylina et al., and respectfully request withdrawal of the outstanding rejection on this basis.

VII. Conclusion.

The points and concerns raised by the Examiner in the outstanding Office Action having been addressed in full, it is submitted that this application is in condition for allowance, which action is respectfully requested. Should the Examiner have any remaining concerns, it is respectfully requested that the Examiner contact the undersigned attorney to expedite the prosecution of this application to allowance.

Respectfully submitted,



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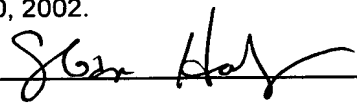


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Sloan Hobbs



Inventor: Lanahan et al.
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Version with Markings to Show Changes Made

In the Specification.

Please amend the paragraph at page 28 (line 29) through page 29 (line 9) as follows.

-- In the present invention, the hyperthermophilic α -galactosidase described herein may be added to the animal feed at any point in feed or meal processing following removal of hulls, shells or skins from, for example, soybeans, other beans, legumes, corn, wheat, oat, beet, canola, rice or other grains or protein sources, up to and including pelleting or extrusion of the animal feed. For example, the hyperthermophilic α -galactosidase may be added when the various ingredients of the feed are being combined. The only limitation on what point in the feed processing the hyperthermophilic α -galactosidase may be added is that the enzyme must be added prior to a processing step carried out under high temperature (*i.e.*, higher than about 60°C, 70°C, 75°C or 80°C) conditions. Preferably, the hyperthermophilic α -galactosidase is added prior to any steam treatment that the components of animal feed [or animal feed] may undergo during processing. --

In the Claims.

Please amend the claims as follows.

1. (Amended) A method of hydrolyzing a galactose-containing oligosaccharide present in a substrate intended for use as an animal feed or human food, comprising:

contacting the substrate with a hyperthermophilic α -galactosidase isolated from the group consisting of *Thermotoga maritima*, *Thermotoga elfii*, and *Thermotoga* sp. T2; and

heating the substrate to a temperature at which the hyperthermophilic α -galactosidase is active, for a period of time sufficient to hydrolyze the oligosaccharide.

51. (Amended) A method of preventing gastrointestinal distress in a mammal, wherein the gastrointestinal distress is caused by a feed or food containing at least one oligosaccharide selected from the group consisting of raffinose, stachyose and verbascose, comprising:

contacting the feed or food with a hyperthermophilic α -galactosidase isolated from the group consisting of *Thermotoga maritima*, *Thermotoga elfii*, and *Thermotoga* sp. T2; and then

heating the feed or food for a period of time sufficient to allow the hyperthermophilic α -galactosidase to hydrolyze the oligosaccharide.
